

## **Pharmaceutical Market Access and Drug Safety Act (S. 334)**

### **I. Importable Drugs:**

- Drugs must be approved by the Food and Drug Administration and manufactured in an FDA-inspected plant.
- Drugs must be patient-administered and not a controlled substance, an infused or injected drug, a biologic, or a drug inhaled during surgery.

### **II. Commercial importation by pharmacies and drug wholesalers:**

- Allows importation by licensed pharmacies and drug wholesalers from Canada, the European Union, Australia, New Zealand, Japan, and Switzerland beginning one year from enactment.
- Requires registration of wholesalers and pharmacies with FDA, and levies capped fees to support the costs of the program. Registration may only be of those entities that are fully licensed in accordance with applicable state and federal law to act as pharmacies or wholesalers of prescription drugs.
- Importers and all resellers of imported products must provide a full chain-of-custody (pedigree), tracking possession of drugs from the point of manufacture to the sale to the consumer.
- Drugs must be re-labeled in English to comply with FDA requirements. The FDA will provide approved labeling information to importers.
- FDA may ban the importation of a product that has been determined to be counterfeit, contaminated, or is otherwise adulterated so as not to meet the requirements of this legislation. FDA may require use of approved anti-counterfeiting technologies to verify the chain-of-custody of a drug.
- This bill specifically protects pharmacies, wholesalers, and individuals from patent damages arising from the importation of drugs.

### **III. Personal importation by individuals:**

- Beginning 90 days from enactment, individuals may be shipped prescription drugs purchased via mail-order or websites from Canadian pharmacies registered with the FDA. These Canadian exporters will be fully inspected and approved by the FDA. Canadian pharmacies must validate a U.S. prescription, review health and medication history, and track shipments.
- The bill also would not change the current practice of American consumers traveling to foreign countries such as Canada and Mexico and returning with 90-day supplies of medicines for their personal use, as the FDA currently allows under its “personal use” enforcement policy.

#### **IV     A Gaming@ the system:**

- The bill protects those selling or using drugs imported under the program by preventing an individual from taking discriminatory actions that would have the effect of thwarting drug importation. Such an action against a pharmacist, wholesaler, or consumer to hinder their importation of prescription drugs will be an unfair and discriminatory practice, and treble economic damages may be awarded. The bill makes it clear that a drug manufacturer is not compelled to sell its product in a country.
- The proposal includes features to prevent a drug manufacturer from blocking importation of drugs, such as by changing the color, dosage form, or place of manufacture of the drug so that it is no longer FDA-approved. Drug manufacturers that make these kinds of changes would be required to notify the FDA, and the FDA would be given the authority to take the steps needed to approve the drug.

#### **V.     Limiting unsafe drug imports:**

- Customs could seize and destroy small quantities of drugs imported by individuals from foreign exporters that are not registered with the FDA. The FDA would provide the individual whose drugs were seized with a simple notice explaining how the individual can import drugs from registered Canadian exporters safely and legally.

#### **VI.    Funding for implementation:**

- Funding for the FDA to administer the drug importation safety system created under this bill would be fully financed by user fees on registered importers (U.S. licensed pharmacies or drug wholesalers) and Canadian exporters (registered Canadian pharmacies).

#### **VII.   Domestic Internet pharmacy consumer protections:**

- Sets new disclosure standards for domestic Internet pharmacies.
- Bars domestic Internet sites from selling or dispensing prescription drugs to consumers who are provided a prescription solely on the basis of an on-line questionnaire.
- Would allow state Attorneys General to go to federal court to shut down rogue domestic Internet pharmacy sites.